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Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Activity

No disciplinary matters were brought to conclusion between the dates of December 1, 2004, and March 1, 2005.

Board Begins Rule Making Process

The Minnesota Board of Pharmacy has taken the first steps in what will likely prove to be a lengthy rule making process to update Board rules in many different areas.

Preliminary discussions have identified over 30 different subject areas for new rules, changes to existing rules, or deletion of rule sections.

The rule making process in Minnesota is a lengthy one and provides multiple opportunities for input from stakeholders who are likely to be impacted by the proposed changes. Later this spring and over the summer, the Board anticipates bringing together a number of pharmacists to discuss various sections of the proposed rule modifications. Once a general consensus is reached on proposed language, the Board will formally publish its Notice of Intent to Adopt Rules and the exact language for each of the proposed changes will become available. The opportunity will then be available for members of the public and the pharmacy community to provide comment on the proposed rule language. It is unlikely that the rule changes will be implemented fully until late in 2005 or early in 2006.

Some of the major areas that the rule package will be addressing are briefly discussed below:

- Computerized Physician Order Entry. By this time a substantial number of pharmacists around the state have received prescriptions that were generated by computer in a physician's office. Some of these prescriptions are faxed directly to the pharmacy by the physician's computer system, while others have been printed out at the physician's office and handed to the patient after being entered in either a hand-held device or on a laptop or desktop computer by the prescriber. Of concern is how a pharmacist who receives an electronically signed prescription that has been printed out and handed to the patient is able to verify that this is the one and only copy of that prescription and that the physician has, in fact, entered the data.

  The Minnesota Legislature has addressed the issue of the validity of electronically signed documents and has developed some standards for electronic documents that would seemingly be applicable to electronically signed prescriptions. Of particular interest is the requirement that both parties involved in the transaction must agree to accept electronically signed documents. As applied to computerized physician-generated prescriptions, this requirement would seem to indicate that both the physician and the pharmacist must agree to accept electronically signed communications.

  Drug Enforcement Administration (DEA) has been developing standards for computerized physician-generated prescriptions for controlled substances for a number of years. Many state boards of pharmacy including Minnesota have delayed developing rules relating to electronic prescribing in the hopes that DEA would implement its rules shortly. It now appears that DEA's proposals, which would apply nationwide to all controlled substance prescriptions, are not imminent.

  As a result of the above, the Board will attempt to address the issue of computerized physician order entry.
- Telepharmacy Systems. The Board has received several requests from pharmacists to expand professional services to underserved areas through the implementation of telepharmacy systems. Until now, the pharmacists involved have submitted appropriate variance requests to the Board.

  In an effort to provide some standardization in the development of telepharmacy systems, the Board will be considering the development of rules establishing minimum standards for expansion of pharmacy services through telepharmacy technology.
- Central Fill Services. There are now several pharmacies in Minnesota providing central fill prescription services to other pharmacies. Currently, there are no rules relating to central fill services and, hereto, the Board has been addressing these on a case-by-case basis. The Board sees a need for standardization, to the extent possible, of central fill pharmacy activities and will attempt to develop rules relating to operating standards for central fill pharmacy services.
- The United States Pharmacopeia (USP) recently developed and published standards for prescription compounding and for the compounding of sterile products in pharmacies. These two new sections of the United States Pharmacopeia – National Formulary, Chapters 795 and 797, respectively, have, by virtue of the action of the USP, become the standard of practice throughout the United States. The Board will be developing rule sections addressing these issues with the aim of helping Minnesota pharmacies come into compliance with these national standards.
- Technician Education/Training. More and more states are developing uniform education and training requirements for pharmacy technicians. To date, Minnesota has not developed any minimum educational requirements applicable to pharmacy technicians and, while recognizing the value of a certificate earned by a pharmacy technician through the Pharmacy

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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Technician Certification Board (PTCB), such certification is still voluntary. Recent statistics show that between one-third and one-half of all technicians in Minnesota have received certification from PTCB and there appears to be support for uniform education and training.

In addition to attempting to develop education and training requirements for pharmacy technicians, the Board will also explore areas in which technicians can assume additional responsibilities within the pharmacy.

- Adverse Health Event Reporting. The Minnesota Legislature recently passed a requirement that Minnesota hospitals report all adverse health events (including medication errors) to the Minnesota Department of Health while allowing the hospitals a certain amount of confidentiality in the reporting. The Board will be exploring whether or not adverse health events occurring in pharmacy settings outside of the institutional setting should be reported to the Board.
- Continuing Education. Two issues dealing with continuing education (CE) will be addressed during the Board's deliberations on potential rule changes. First, the Office of the Inspector General (OIG) has criticized the role and manner in which drug manufacturers engage in CE activities and has called on drug manufacturers to relinquish any control they may have had over the content and speakers for CE programming. The OIG is suggesting that drug manufacturers limit their participation to grants made to independent CE program providers who, in turn, will identify speakers and program content.

  Later this year, the Accreditation Council for Pharmacy Education (ACPE) will discontinue accepting drug companies as approved CE providers. ACPE recognized that drug manufacturers cannot meet both ACPE's standards for approved CE providers and the recommendations of the OIG at the same time.

  The question before the Board, then, is whether or not it should discontinue accepting CE programming sponsored directly by drug manufacturers or their representatives at the state level.

  The second CE issue is the Board's consideration of a recommendation made by the Continuing Education Advisory Task Force to the Board that those pharmacists seeking an extension of time in which to complete their CE be assessed a $100 fee to recover the cost of the additional paperwork and staff time such requests involve. It has been the Board's experience that most pharmacists requesting an extension of time to complete their CE have no valid excuse for not completing their CE in a timely fashion and the recommendation of the Continuing Education Advisory Task Force is that assessing a fee to recover the additional costs undertaken by the Board in processing the extension requests might encourage pharmacists to complete their CE on time.
- Mandatory Patient Counseling. It has been the Board's observation that the amount of documented patient counseling being performed by Minnesota pharmacists is less than optimal. Comments have been made to the Board by pharmacists transferring to Minnesota from other states to the effect of, "In state X patient counseling is mandatory and we counsel every patient who receives a new prescription and most patients who receive prescription refills. In Minnesota, I'm surprised at the lack of patient counseling."

  Case in point: One of the Board inspectors had a spouse who recently received two new prescriptions and went to a local chain pharmacy to have the prescriptions filled. The pharmacist did not come to speak to the individual, so the individual asked to speak to the pharmacist, who simply said something to the effect of, "Everything you need to know is on the printout that is in your prescription bag." Not only is this inadequate from the patient's point of view, but it is a violation of that pharmacy chain's internal policies that dictate that the pharmacist will counsel the patient on all new prescriptions. In Minnesota, patient counseling is not occurring to the extent that it should and the Board has identified the lack of mandatory counseling as a major factor.

As can be seen from this brief list of some of the subject areas under consideration by the Board for rule development, significant discussions lie ahead. Every attempt will be made to keep Minnesota pharmacists informed of the direction of the rule making process as the Board meets with the various stakeholder groups to discuss these proposals.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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